K063485

510(k) SUMMARY

DEC - 1 2006

510(k) NUMBER: PENDING

SUBMISSION TYPE: Traditional

SUBMITTED BY:
Surgical Innovations Group plc
Clayton Park
Clayton Wood Rise
LEEDS
LS16 6RF
Tel: + 44 (0) 113 2307 597
Fax: + 44 (0) 113 2307 598

CONTACT PERSON:
Stuart Moran
Joint Managing Director

DATE OF PREPARATION: 10th September 2006

NAME OF DEVICE: Laparoscopic Monopolar Scissors

CLASSIFICATION NAME: Device, Electrosurgical, Cutting & Coagulation & Accessories (Regulation Number 21CFR 878.4400)

TRADE NAME: Logic Laparoscopic Scissors

PREDICATE DEVICES: Applied Medical Laparoscopic Monopolar Scissors which is cleared to market under premarket notification K040295

Aesculap Resposable Instrument System which is cleared to market under premarket notification K014207

INDICATIONS FOR USE:
Surgical Innovations Resposable Laparoscopic Scissors are designed to cut, dissect, manipulate and/or cauterize various tissue during endoscopic/laparoscopic, general, vascular gynaecological and thoracic surgical procedures.

SUMMARY STATEMENT:
Surgical Innovations Resposable Laparoscopic Scissors are designed to cut, dissect, manipulate and/or cauterize various tissue during endoscopic/laparoscopic, general, vascular gynaecological and thoracic surgical procedures. The Logic Resposable Laparoscopic Scissors consist of a reusable handle and disposable insulated shaft with scissor blades. The device has a 5mm diameter disposable insulated shaft that connects to a reusable Polyenylsulfone/stainless steel handle with a male cautery connector to be utilised for monopolar cautery when attached to standard monopolar cautery cables and their generators.

The disposable shaft consists of an aluminium outer shaft housing a stainless steel actuation rod, which connects to the scissor blades and handle actuation rod. The disposable shaft is to be supplied sterile in single unit pouches. The scissors will be available in working lengths of 24cm, 32cm and 42cm.

The reusable handle is steam sterilized by the user and then connected to the sterile disposable shaft. Following use the shaft and handle are disassembled. The shaft is disposed of and the handle is cleaned and re-sterilised.

The device is in compliance with ISO 10993 for Biocompatibility. The Logic Laparoscopic Scissors shaft is sterilised using gamma irradiation which provides a sterility assurance level of 10^{-6}.

The Laparoscopic Scissor handle is provided non-sterile. Sterilisation instructions are provided in the instructions for use. The Surgical Innovations steam sterilisation and cleaning validation methods are based on the AAMI TIR No 12-1994, Designing, Testing and Labelling Reusable Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufactures and proves a sterility assurance level of 10^{-6}. Sterilisation validation of the steam sterilisations is based on three sterilisation cycles at one half the exposure time. The use of Bacillus sterothermophilus spore strips or inoculum is the utilised indicator.

The Logic Resposable Laparoscopic Scissors are substantially equivalent the Applied Medical Laparoscopic Monopolar Scissors which is cleared to market under premarket notification K040295 and the Aesculap Resposable Instrument System which is cleared to market under premarket notification K014207 in terms of intended use, design and use methodology and are manufactured from similar materials.

Surgical Innovations is the manufacturer of the device and has followed design control regulations per 21 CFR § 820.30. The design controls have been in place since 1998 and have been audited by FDA on several occasions. The design of the Logic Resposable Laparoscopic Scissors was within the Surgical Innovations Design Control System.

A design Risk Assessment was conducted in accordance with Surgical Innovations internal Stand Operating Procedures, ISO 9001/ISO 13485, ISO 14971 and 21 CFR § 820.30, validation and verification activities addressed in the profile. Based on the risk analysis, validation and verification activities were formally controlled and addressed by Surgical Innovations, the activities included the methods, tests used and acceptance criteria applied.

REVIEW OF PERFORMANCE DATA

Cutting performance

It is essential that laparoscopic scissors are sharp, are capable of withstanding electrocautery (diathermy) energy transfer, and are suitable for cutting a range of tissue types. Furthermore, Surgical Innovations has undertaken a range of bench tests to determine the cutting performance and compliance with the ASTM Standards. The sharpness of the scissors is standardised in ASTM F1079-87 (1993). TN100047 summaries the testing undertaken and demonstrates compliance with ASTM F1079-87 (1993).

The cutting life of the scissors is also important and TN100046 demonstrates a life 2,400 cuts into latex rubber (generally regarded as an indicator of the sharpness of a product.

Therefore, the Logic Resposable Scissors comply with ASTM1079 and have a life deemed to be sufficient to cope with almost all laparoscopic procedures.

Electrical Safety

The electrical safety of the product is paramount. Both the scissor shaft and handle have been tested in accordance with EN60601-2-2 and EN60601-2-18 (see TN100048, TN100055 and TN100034 respectively).

In conclusion the complete device is deemed to be compliant with the relevant parts of EN60601 and therefore deemed safe.

Temperature Performance

The performance of the insulation is also very important. This can be damaged by excessive heat. The heat generation resulting of excessive coagulation was investigated in TN100044 and TN100049. The performance of the insulation was deemed to be sufficient to withstand excessive heat generation during surgery.

Conclusion

It can be concluded from the above bench testing that the product performs well and is fit for purpose.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Surgical Innovations Plc
% Intertek Testing Services
Mr. Daniel W. Lehtonen
2307 East Aurora Road
Twinsburg, Ohio 44087

DEC 1 2006

Re: K063485
Trade/Device Name: Laparoscopic Monopular Scissors
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: November 16, 2006
Received: November 17, 2006

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Laparoscopic Monopular Scissors

Indications For Use: Surgical Innovations Resposable Laparoscopic Scissors are designed to cut, dissect, manipulate and/or cauterize various tissue during endoscopic/laparoscopic, general, vascular gynaecological and thoracic surgical procedures.

Prescription Use (Part 21CFR801 Subpart D) ✓ AND/OR Over-The-Counter Use (Part 21CFR801 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Ann MD for MKA

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063485